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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/220,275	12/23/1998	STEPHEN H. FRIEND	9301-039-999	3713

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EXAMINER

MARSCHIEL, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/19/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/220,275

Applicant(s)

Friend et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 30, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-64 and 70-76 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-61 and 71-73 is/are rejected.
- 7) ☒ Claim(s) 62-64, 70, and 74-76 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO 413) Paper No(s). 17
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20) ☐ Other:

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 1/30/02, has been entered.

Applicants' arguments, filed 1/30/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 58-61 and 71-73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Felder et al. (P/N 6,232,066) alone; or, alternatively, taken in view of Singer et al. (P/N 5,866,331).

Felder et al. is directed to high throughput screening including concurrent assay practice with arrays of probes as summarized in the abstract. A variety of possible probes is listed in column 4, lines 7-62, including target substances which are cellular substituents. The high throughput assays of Felder et al. include drug evaluation or testing as noted in column 1, lines 44-51. The simultaneous performance of biological assays of the reference is also summarized in column 2, lines 10-48. The assay of cellular mRNA species in the reference is specifically summarized in column 16, lines 16-43. The testing of drugs on cells which are then subjected to mRNA extraction followed by array hybridization to cellular constituents is set forth in column 16, line 44, through column 17, line 16. Such array assay results are reasonably biological response profiles as instantly claimed wherein living cells or organisms are being tested. Felder et al. additionally discusses the use of controls to fine tune the assay results in column 23, line 41, through

column 24, line 23. Thus, the comparison to various control probes etc. is motivated by Felder et al. to remove artifacts or undesired signals by comparison to these controls thus leaving the desired experimental data signals. One such undesired signal is the background signal. In column 33, lines 17-30, a fluorescence experiment is summarized including the subtraction of background signal for each spot in a multiwell plate assay. In instant claim 58, the artifact pattern which is subtracted from the measurements in the profile is removed so that deviation of experimental values from desired values is obtained. One reasonable interpretation of desired values are signals for each determination in a profile which corresponds only to the drug or perturbation effect on the living cells being assayed. Clearly, any background signal is a undesired signal as it does not reflect any drug or perturbation effect on said cells. Thus, example of Felder et al. motivates the subtraction of such background signal values in the plurality of hybridization assays of the reference thus resulting in the practice of the instant invention.

Additionally to Felder et al. is the Singer et al. reference which is also directed to the evaluation of signals in hybridization assays. In column 6, line 55, through column 7, line 12, fluorescent signals are also corrected for measurement artifacts such as dark current subtraction as well as other

signal processing to result in the proper experimental values. It is noted that different filters and fluorescent measurements are described in Singer et al. supporting the concept that the background subtraction would have to be determined from a library or via the selection from a list corresponding to the filters or fluorescence being measured.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to process hybridization signals, including background subtraction, to obtain multiple assay profiles resultant from perturbations such as in drug testing on live cells as suggested in Felder et al. alone, or, alternatively, reinforced for such fluorescent signal processing as in Singer et al. to result in the above instant claim practice.

58-61 and 71-73

Claims 62-64, 70, and 74-76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center


number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

April 18, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER